

Remarks

Claims 1-11 and 13-37 are pending.

The amendment to claim 1 is supported by the specification at page 5, lines 20-22 and page 11, lines 29-31. The amendment to claim 6 is supported by claim 13 as filed. The amendment to claim 7 is supported by page 12, lines 12-13. The amendments to claims 23 and 24 are supported by the specification at page 8, lines 1-5. The amendment to claim 29 is supported by page 14, lines 7-9. The new claim 37 is supported by claim 24 as filed.

Applicants submit that the amendments to claims 7 and 29 would not narrow the scope of the amended recitations because a person skilled in the art would have been understood that the only solvent in step (i) in the process of claim 6 or 23 is the first solvent.

Claim Objections

The undersigned would like to thank Examiner Kumar for holding that claims 34-36 would be allowed if made independent of the rejected base claims. Claims 34-36 have been made independent of claims 1, 6 and 23, respectively. Withdrawal of the objection is requested.

Claim Rejection -- 35 U.S.C. 102

Applicants respectfully traverse the anticipatory rejection of claims 1 and 3 over Ekwuribe et al (US 6,479,692; hereinafter US '692). US '692 discloses a process of preparing a genus of acylanilides of formula V, which includes bicalutamide (see column 2, line 28 to column 3, line 65). US '692 discloses crystallization of bicalutamide in ethyl acetate-petroleum ether (column 13, lines 55-57). US '692 fails to anticipate claims 1 and 3 because the processes of claims 1 and 3 do not use ethyl acetate and petroleum ether. US '692 does not teach or suggest using the solvent recited in step (i) of claim 1. Withdrawal of the anticipatory rejection is requested.

Claim Rejections -- 35 U.S.C. 103

Applicants respectfully traverse the obviousness rejection of claims 1-32 over US '692, Tucker (US 4,636,505) and Keil et al (US 5,300,652).

US '692 differs from claims 1-11 and 13-33 in not teaching the use of the solvents recited therein for crystallizing bicalutamide.

Tucker discloses a genus of acylanilides which includes bicalutamide (see Abstract). Tucker discloses the use of toluene and petroleum ether to crystallize some of the species within the genus of acylanilides (see column 8, lines 29-30 and 60-61).

Claims 1-11 and 13-33 do not recite the use of ethyl acetate and petroleum ether, or a mixture of toluene and petroleum ether in crystallizing bicalutamide. Tucker also differs from claims 1-11 and 13-32 in not teaching the use of the solvents recited therein for crystallizing bicalutamide.

The Office Action relies on Keil et al for the disclosure of using seeding in crystallization of an acylanilide containing a pyrazole group (see Abstract and column 1, lines 51-52). However, the acylanilide of Keil et al contains a pyrazole group and no sulfonyl group. In contrast, bicalutamide contains no heterocyclic group, let alone pyrazole group. Bicalutamide also contains a sulfonyl group not found in the acylanilide of Keil et al. With these structural differences, applicants submit that a person of ordinary skill in the art would not have used the disclosure of Keil et al to modify the processes of US '692 and Tucker to arrive at the claimed processes.

Thus, there would have been no suggestion or motivation to modify the processes of US '692, Tucker and Keil et al to arrive at the processes of claims 1-11 and 13-33. Withdrawal of the obviousness rejections is requested.

In addition, claims 6-11 and 13-33 further differ from US '692, Tucker and Keil et al in that claims 6-11 and 13-33 require two solvents recited in the claims. US '692, Tucker and Keil et al do not teach or suggest using the two solvents recited in the claims to crystallize bicalutamide. US '692, Tucker and Keil et al especially do not teach or suggest using one solvent and an anti-solvent to crystallize bicalutamide. These are additional reasons why claims 6-11 and 13-33 should not have been rejected as obvious over US '692, Tucker and Keil et al.

In the event that this Amendment is deemed not timely, applicants petition for an appropriate extension to time. The petition fee, and any other fees that may be required in relation to this Amendment, can be charged to Deposit Account No. 11-0600. The Examiner is

urged to call the undersigned in the event that there remains any minor issues that can be resolved with a telephone interview.

Respectfully Submitted,
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